MAY 1 3 2013

3. 510(k) Summary

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807 Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person

Philips Ultrasound, Inc.
3000 Minuteman Road
Andover, MA
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Date prepared: January 21, 2013

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:	Picture Archiving and Communications Systems Workstation
Proprietary Name:	QLAB Quantification Software with Heart Model
Classification Name:	CFR 892.2050, system, image processing, radiological, Product code LLZ, Class II

3) Substantially Equivalent Devices

Philips Ultrasound believes that the QLAB software with the Heart Model application is substantially equivalent to other commercially available products, including Philips QLAB Cardiac 3DQ and 3DQA (K040227 & K042540), Philips Brilliance CT (K042293), and Siemens *syngo* US Workplace (K091286).

4) Device Description

The QLAB software application is available either as a stand-alone product that can function on a standard PC, a dedicated workstation, and on-board Philips' ultrasound systems. It can be used for the on-line and off-line review and quantification of ultrasound studies.

QLAB Quantification software now includes the Heart Model application.

Heart Model
The Heart Model application provides automatic 3D anatomical segmentation and identification of the heart chambers for the End Diastole (ED) and End Systole (ES) cardiac phases. The Heart Model segmentation algorithm draws segmented borders for select standard American Society of Echocardiology (ASE) apical and short axis views. This provides a streamlined workflow for obtaining cardiac 3D quantitative heart chamber measurements and calculated result values.

5) Intended Use
QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips Healthcare ultrasound products.

6) Technological comparison to predicate devices
QLAB Heart Model algorithm is reused from Philips Brilliance CT (K042293), but modified for ultrasound. It is similar to QLAB 3DQ/3DQA and the Brilliance CT Comprehensive Cardiac Analysis (CCA) in that the user is able to evaluate the image in the ASE/ESE American Society of Echocardiography and European Society of Echocardiography standard views display. While 3DQ requires the user to place reference points to finish a trace, QLAB Heart Model finds the chambers of the Heart and then displays the Heart Model determined chamber borders in the ASE/ESE views for the user to Accept or Reject. Similar to Siemens *syngo* US Workplace, QLAB Heart Model automatically generates left atrial (LA) and left ventricular (LV) volumes.

7) Non-clinical performance data
No performance standards for PACS systems or components have been issued under the authority of Section 514. The Heart Model application was tested in accordance with Philips verification and validation processes. Quality assurance measures were applied to the system design and development, including:

- Risk Analysis
- Product Specifications
- Design Reviews
- Software Verification & Validation

Summary of Clinical Tests:
The subject of this premarket submission, QLAB Heart Model, was clinically evaluated and accepted during external validation and determined to be as safe and effective as predicate devices.

External clinicians evaluated the functionality and performance of Heart Model. The external evaluation confirmed that Heart Model met its intended use and that the LA and LV chamber measurements correlated to cardiac MRI.

8) General Safety and Effectiveness Concerns

The device labeling contains operating instructions for the safe and effective use of the QLAB software with Heart Model.

9) Conclusions

The QLAB Quantification Software with the Heart Model application incorporates components common to all image viewing systems for the display and quantification tasks within a clinical setting. Software development for the QLAB software follows documented processes for software design, verification and validation testing. A risk assessment was completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of image display and quantification product. Verification and validation activities of the QLAB Quantification software with the Heart Model application indicate that it meets its intended use and introduces no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

Philips Ultrasound, Inc.
% Ms. Penny Greco
Regulatory Affairs Specialist
Philips Healthcare
3000 Minuteman Road
ANDOVER MA 01810

Re: K130159
Trade/Device Name: QLAB Quantification Software Heart Model
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 25, 2013
Received: March 28, 2013

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130159

Device Name: QLAB Quantification Software

Indications for Use:

QLAB Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips Healthcare ultrasound products.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K130159